# NIX- permethrin rinse Insight Pharmaceuticals LLC

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**Nix Creme Rinse - 63736-030** 

# **Drug Facts**

# Active ingredient (in each fluid ounce)

Permethrin 280 mg (1%)

# **Purpose**

Lice treatment

#### Use

treats head lice

# Warnings

# For external use only

#### Do not use

- on children under 2 months of age
- near the eyes
- inside the nose, ear, mouth, or vagina
- on lice in eyebrows or eyelashes. See your doctor.

# Ask a doctor before use if you are

allergic to ragweed. May cause breathing difficulty or an asthmatic episode.

# When using this product

- keep eyes tightly closed and protect eyes with a washcloth or towel
- if product gets into the eyes, immediately flush with large amounts of water
- scalp itching or redness may occur

# Stop use and see a doctor if

- breathing difficulty occurs
- eye irritation occurs
- skin or scalp irritation continues or infection occurs

# If pregnant or breast-feeding,

ask a health professional before use.

# Keep out of reach of children.

If swallowed, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

# **Directions**

# Important: Read warnings before use

# Adults and children 2 months of age and over:

# Inspect

- all household members should be checked by another person for lice and/or nits (eggs)
- use a magnifying glass in bright light to help you see the lice and nits (eggs)
- use a tool, such as a comb or two unsharpened pencils to lift and part the hair
- look for tiny nits near the scalp, beginning at the back of the neck and behind the ears
- small sections of hair (1-2 inches wide) should be examined at a time
- unlike dandruff, nits stick to the hair. Dandruff should move when lightly touched.
- if either lice or nits (eggs) are found, treat with Nix<sup>®</sup> Creme Rinse

#### **Treat**

- wash hair with a shampoo without conditioner. Do not use a shampoo that contains a conditioner or a conditioner alone since this may decrease the activity of Nix<sup>®</sup>. Rinse with water.
- towel dry hair so it is damp but not wet
- shake the bottle of Nix<sup>®</sup> well
- completely saturate the hair and scalp with Nix<sup>®</sup>. Begin to apply Nix<sup>®</sup> behind the ears and at the back of the neck.
- keep Nix<sup>®</sup> out of the eyes. Protect the eyes with a washcloth or towel.
- leave Nix<sup>®</sup> on the hair for 10 minutes, but no longer
- rinse with warm water
- towel dry hair and comb out tangles
- if live lice are seen seven days or more after the first treatment, a second treatment should be given

#### Remove Lice/Nits

- remove nits by combing the hair with the special small tooth comb provided. Remaining nits may be removed by hand (using a throw-away glove), or cutting the nits out.
- use the nit comb provided and make sure the hair remains slightly damp while removing nits
- if the hair dries during combing, dampen it slightly with water
- part the hair into 4 sections. Work on one section at a time. Longer hair may take more time (1-2 hours).
- start at the top of the head on the section you have picked
- with one hand, lift a 1-2 inch wide strand of hair. Get the teeth of the comb as close to the scalp as possible and comb with a firm, even motion away from the scalp to the end of the hair.
- use clips to pin back each strand of hair after you have combed out the nits
- clean the comb completely as you go. Wipe the nits from the comb with a tissue and throw away the tissue in a sealed plastic bag to prevent the lice from coming back.
- after combing, recheck the entire head for nits and repeat combing if necessary
- check the affected head daily to remove any nits that you might have missed

#### Other information

- read all the directions in the Consumer Information Insert and warnings before use. Keep the carton. It contains important information.
- store at 20° to 25°C (68° to 77°F)

# **Inactive ingredients**

canada balsam, cetyl alcohol, citric acid, FD&C yellow no. 6, fragrance, hydrolyzed animal protein, hydroxyethylcellulose, polyoxyethylene 10 cetyl ether, propylene glycol, stearalkonium chloride, water, isopropyl alcohol, methylparaben, and propylparaben

# Questions or comments?

Call 1-888-LICE LINE (1-888-542-3546), Monday to Friday, 9 AM - 5 PM EST

# PRINCIPAL DISPLAY PANEL

Nix<sub>®</sub>

# Lice Killing Creme Rinse

includes 1 bottle plus 1 nit comb NET WT 2 FL OZ (59 mL)



# PRINCIPAL DISPLAY PANEL

Nix<sub>®</sub>

# **Creme Rinse – Family Pack**

Permethrin/Lice Treatment

Family Pack - NET WT 4 FL OZ (2 - 2 FL OZ (59 mL)



# NIX

permethrin rinse

# **Product Information**

Product Type HUMAN OTC DRUG Item Code (Source) NDC:63736-030

Route of Administration TOPICAL

# **Active Ingredient/Active Moiety**

Ingredient NameBasis of StrengthStrengthPERMETHRIN (UNII: 509 F88 P9 SZ) (PERMETHRIN - UNII: 509 F88 P9 SZ)PERMETHRIN1 g in 100 mL

# Ingredient Name CANADA BALSAM (UNII: K304VI98I3) CETYL ALCOHOL (UNII: 936JST6JCN) CITRIC ACID MONOHYDRATE (UNII: 2968PHW8QP) FD&C YELLOW NO. 6 (UNII: H77VEI93A8) PROPYLENE GLYCOL (UNII: 6DC9Q167V3) STEARALKONIUM CHLORIDE (UNII: 00U026BB88)

| WATER (UNII: 059QF0KO0R)             |  |
|--------------------------------------|--|
| ISOPROPYL ALCOHOL (UNII: ND2M416302) |  |
| METHYLPARABEN (UNII: A2I8 C7HI9 T)   |  |
| PROPYLPARABEN (UNII: Z8IX2SC1OH)     |  |

| Product Characteristics |                       |              |  |  |
|-------------------------|-----------------------|--------------|--|--|
| Color                   | ORANGE (Light Orange) | Score        |  |  |
| Shape                   |                       | Size         |  |  |
| Flavor                  |                       | Imprint Code |  |  |
| Contains                |                       |              |  |  |

| P | Packaging        |  |                             |                    |  |  |
|---|------------------|--|-----------------------------|--------------------|--|--|
| # | Item Code        | Package Description                                  | <b>Marketing Start Date</b> | Marketing End Date |  |  |
| 1 | NDC:63736-030-01 | 1 in 1 CARTON  | 11/15/2013                  |                    |  |  |
| 1 |                  | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product |                             |                    |  |  |
| 2 | NDC:63736-030-02 | 2 in 1 CARTON  | 11/15/20 13                 |                    |  |  |
| 2 |                  | 59 mL in 1 BOTTLE; Type 0: Not a Combination Product |                             |                    |  |  |

| Marketing Information |  |                      |                    |  |  |
|-----------------------|--|----------------------|--------------------|--|--|
| Marketing Category    | Application Number or Monograph Citation | Marketing Start Date | Marketing End Date |  |  |
| NDA                   | NDA0 19 9 18                             | 11/15/2013           |                    |  |  |
|                       |  |                      |                    |  |  |

# **Labeler** - Insight Pharmaceuticals LLC (055665422)

Revised: 4/2020 Insight Pharmaceuticals LLC